

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA, :
: Plaintiff,
: v.
: Defendant.
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ECF CASE

Case No. 10 Civ.7450 (LAP)

STIPULATION AND ORDER OF SETTLEMENT AND DISMISSAL

This Stipulation and Order of Settlement and Dismissal ("Stipulation") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS"), the Defense Health Agency ("DHA") acting on behalf of the TRICARE Program, the Office of Personnel Management ("OPM"), which administers the Federal Employees Health Benefits Program ("FEHBP"), the United States Department of Veteran Affairs ("VA") (collectively the "United States"), Inspire Pharmaceuticals, Inc. ("Inspire"), and Jill DeGuzman ("Relator") (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. Inspire is a Delaware corporation with its principal place of business at 1925 West Field Court, Lake Forest, IL, 60045. Prior to its acquisition by Merck & Co., Inc., in May 2011, Inspire had its principal place of business in Durham, North Carolina, and engaged in the development, distribution, and sale of pharmaceutical and health care products, including its drug AzaSite®, throughout the United States.

B. On September 29, 2010, the Relator filed a *qui tam* action on behalf of the United States in the United States District Court for the Southern District of New York captioned *United States ex rel. J. Doe, et al. v. Inspire Pharmaceutical, Inc.*, 10 Civ. 7450 (LAP), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Civil Action”). In addition, the *qui tam* action also named as plaintiffs the states of Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Oregon, Rhode Island, Tennessee, Texas, Virginia, Wisconsin (collectively, the “States”) and the District of Columbia. The United States intervened in the Civil Action on or around June 10, 2015 and filed the United States’ Complaint on or around June 10, 2015 (the “Government’s Complaint”).

C. The United States contends that for the period of January 1, 2008, through September 30, 2011, it has certain civil claims against Inspire arising from false claims that were submitted to the federal healthcare programs specified below in this Paragraph C as a result of Inspire’s off-label marketing of AzaSite, for the treatment of blepharitis, a use not approved by the Food and Drug Administration (“FDA”) and which was not a medically accepted indication as defined by 42 U.S.C. § 1396r-8(k)(6). Specifically, the Government alleges that Inspire received FDA approval of AzaSite for the treatment of bacterial conjunctivitis (pink eye) and at no point received FDA approval of AzaSite for the treatment of blepharitis, an inflammation of the eyelash follicles along the edge of the eyelid. The Government contends that although the treatment of blepharitis was not an FDA-approved use, Inspire nonetheless marketed AzaSite as a treatment for blepharitis

and other indications with an inflammatory component, and, as a result of the foregoing conduct, Inspire knowingly caused the submission of false and fraudulent claims for AzaSite to be submitted to the Medicare Program (Medicare), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1; the TRICARE Program, 10 U.S.C. §§ 1071-1110a; the FEHBP, 5 U.S.C. §§ 8901-8914; and the Medicaid Program (Medicaid), 42 U.S.C. §§ 1396-1396w-5; and caused the purchase of AzaSite by the VA under the Veterans Affairs Program, 38 U.S.C. §§ 1701-1743. The conduct described in this paragraph C is referred to below as the Covered Conduct.

D. Simultaneous with this Stipulation, pursuant to which Inspire will pay the United States \$4,938,573.77 plus interest, Inspire and the States will enter into a separate settlement, pursuant to which Inspire will pay the States \$1,021,589.51 plus interest, pursuant to the terms of that settlement to resolve liabilities to the States for the Covered Conduct.

E. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this settlement agreement and to Relator's reasonable expenses, attorneys' fees and costs.

F. To avoid the delay, uncertainty, and expense of protracted litigation of the above claims, the Parties have reached a full and final mutually agreeable resolution of these claims as set forth below.

NOW, THEREFORE, IT IS ORDERED THAT:

1. Inspire consents to this Court's exercise of personal jurisdiction over Inspire.

2. Inspire agrees to pay the United States \$4,938,573.77, and interest on the Settlement Amount at a rate of 2.250% from April 29, 2014 until the date of payment (the “Settlement Amount”). Payment shall be made no later than 30 days after the Effective Date of this Stipulation by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney’s Office for the Southern District of New York.

3. Conditioned upon the United States receiving the Settlement Amount from Inspire and as soon as feasible after receipt, the United States shall pay Relator 20% of the Settlement Amount paid by Inspire pursuant to Paragraph 2 by electronic funds transfer. The Government is not required to pay Relator any portion of the Settlement Amount unless and until the Settlement Amount is paid to the Government by Inspire.

4. Inspire admits, acknowledges, and accepts responsibility for the following during the period from January 1, 2008 through May 11, 2011:

- a. Starting in or around January 1, 2008, Inspire commenced an advertising campaign designed to broaden the customer base for AzaSite by focusing on, among other things, AzaSite’s claimed anti-inflammatory effects, which were not on label.
- b. As the FDA found, Inspire’s claim of anti-inflammatory effects of AzaSite was not demonstrated by substantial evidence or substantial clinical experience. The FDA sent Inspire a letter directing it to cease one of these advertisements as it was “false or misleading because it broadens the indication, makes unsubstantiated claims, and omits and minimizes important risks associated with the use of AzaSite.”
- c. AzaSite was prescribed for blepharitis and claims for such use were submitted for payment to various federal health care programs.

5. Subject to the exceptions in Paragraph 10 (concerning excluded claims) below, and conditioned upon Inspire’s full payment of the Settlement Amount, the United States releases Inspire and all of its parents, subsidiaries, affiliates, and its current and former officers, directors, employees, shareholders, and assigns from any civil or

administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, disgorgement and fraud.

6. Conditioned upon Inspire's full payment of the Settlement Amount, Relator, for herself and for her heirs, successors, attorneys, agents, and assigns, releases Inspire from any liability to Relator arising from the Civil Action or under the False Claims Act, 31 U.S.C. §§ 3729-3733, for the Covered Conduct; provided, however, that nothing in this Stipulation shall preclude Relator from seeking to recover her reasonable expenses and attorneys' fees and costs from Inspire pursuant to 31 U.S.C. § 3730(d) or be deemed to have released her claims under 31 U.S.C. § 3730(d) for such reasonable expenses and attorneys' fees and costs.

7. OIG-HHS expressly reserves all rights to institute, direct, or to maintain any administrative action seeking exclusion against Inspire and/or its officers, directors, and employees from Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) under 42 U.S.C. § 1320a-7(a) (mandatory exclusion), or 42 U.S.C. § 1320a-7(b) or 42 U.S.C. § 1320a-7a (permissive exclusion).

8. DHA expressly reserves all rights to institute, direct, or to maintain any administrative action seeking exclusion against Inspire and/or its officers, directors, and employees under 32 C.F.R. Chapter 199.9.

9. OPM expressly reserves all rights to institute, direct, or to maintain any administrative action seeking debarment against Inspire and/or its officers, directors, and

employees from the FEHBP under 5 U.S.C. § 8902a(b) (mandatory debarment), or (c) and (d) (permissive debarment).

10. Notwithstanding the releases given in paragraphs 5 and 6 of this Stipulation, or any other term of this Stipulation, the following claims of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Stipulation, any administrative liability, including mandatory or permissive exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct; and/or
- e. Any liability based upon obligations created by this Stipulation.

11. Relator and her heirs, successors, attorneys, agents, and assigns shall not object to this Stipulation but agree and confirm that this Stipulation is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B).

Conditioned upon Relator's receipt of the payment described in Paragraph 3, Relator and her heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Stipulation and/or the Civil Action.

12. Inspire waives and shall not assert any defenses Inspire may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Stipulation bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Stipulation constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

13. Inspire fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Inspire has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

14. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier), TRICARE or FEHBP carrier or payer, or any state payer, related to the Covered Conduct; and Inspire agrees not to resubmit to any Medicare contractor, TRICARE or FEHBP carrier or payer, or any state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

15. Inspire agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Inspire, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Stipulation;
- (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Stipulation;
- (3) Inspire's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Stipulation (including attorney's fees);
- (4) the negotiation and performance of this Stipulation; and
- (5) the payment Inspire makes to the United States pursuant to this Stipulation and any payments that Inspire may make to Relator, including costs and attorney's fees.

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, the TRICARE Program, VA Program, and Federal Employees Health Benefit Program (FEHBP) (hereafter referred to as "Unallowable Costs").

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Inspire, and Inspire shall not charge such

Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Inspire or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, VA or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment:

Inspire further agrees that within 90 days of the Effective Date of this Stipulation it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Inspire or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Inspire agrees that the United States, at a minimum, shall be entitled to recoup from Inspire any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Inspire or any of its subsidiaries or affiliates on the effect of inclusion of

Unallowable Costs (as defined in this Paragraph) on Inspire or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Stipulation shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Inspire's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

16. This Stipulation is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 17, below.

17. Inspire agrees that it waives and shall not seek payment for any of the health care billings covered by this Stipulation from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

18. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Stipulation; provided, however, that nothing in this Stipulation shall preclude Relator from seeking to recover her reasonable expenses and attorneys' fees and costs from Inspire pursuant to 31 U.S.C. § 3730(d) or be deemed to have released her claims under 31 U.S.C. § 3730(d) for such reasonable expenses and attorneys' fees and costs.

19. Each party and signatory to this Stipulation represents that it freely and voluntarily enters in to this Stipulation without any degree of duress or compulsion.

20. This Stipulation is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Stipulation is the United

States District Court for the Southern District of New York. For purposes of construing this Stipulation, this Stipulation shall be deemed to have been drafted by all Parties to this Stipulation and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

21. This Stipulation constitutes the complete agreement between the Parties. This Stipulation may not be amended except by written consent of the Parties.

22. The undersigned counsel represent and warrant that they are fully authorized to execute this Stipulation on behalf of the persons and entities indicated below.

23. This Stipulation may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Stipulation. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Stipulation.

24. This Stipulation is binding on Inspire's successors, transferees, heirs, and assigns.

25. This Stipulation is binding on Relator's successors, transferees, heirs, and assigns.

26. The Civil Action and the Government's Complaint are voluntarily dismissed by the Relator and the Government, subject to the terms of this Stipulation. The Civil Action is dismissed with prejudice as to the relator. The Civil Action and the Government's Complaint are being dismissed with prejudice as to the United States with regard to the Covered Conduct released in the Stipulation, and without prejudice as to any other claims.

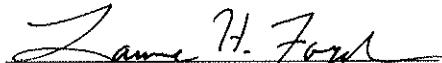
27. The effective date of this Stipulation is the date upon which this Stipulation is entered by this Court (the "Effective Date").

THE UNITED STATES OF AMERICA

Dated: New York, N.Y.

June 12, 2015

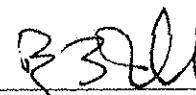
PREET BHARARA
United States Attorney for the
Southern District of New York

By: 
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Dated: Washington, D.C.
May 29, 2015

By: Robert K. DeConti
ROBERT K. DECONTI
Assistant Inspector General
for Legal Affairs
Office of Counsel to
the Inspector General
Office of Inspector General
United States Department of
Health and Human Services

Dated: Falls Church, VA
June 1, 2015

By: 
BRYAN T. WHEELER
Acting General Counsel
Defense Health Agency
United States Department of Defense

Dated: Washington, D.C.
_____, 2015

By: _____
ALAN P. SPIELMAN
Assistant Director of Federal Employee
Insurance Operations
United States Office of
Personnel Management

INSPIRE

Dated: Washington, D.C.
_____, 2015

By: _____
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MITCHELL S. ETTINGER
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1440 New York Avenue, N.W.
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Attorney for Inspire Pharmaceutical, Inc.

Dated: Falls Church, VA
_____, 2015

By: _____
BRYAN T. WHEELER
Acting General Counsel
Defense Health Agency
United States Department of Defense

Dated: Washington, D.C.
June 1, 2015

By: Alan P. Spielman
ALAN P. SPIELMAN
Assistant Director of Federal Employee
Insurance Operations
United States Office of
Personnel Management

INSPIRE

Dated: Washington, D.C.
_____, 2015

By: _____
JOHN T. BENTIVOGLIO
MITCHELL S. ETTINGER
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1440 New York Avenue, N.W.
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Attorney for Inspire Pharmaceutical, Inc.

Dated: Falls Church, VA
_____, 2015

By: _____
BRYAN T. WHEELER
Acting General Counsel
Defense Health Agency
United States Department of Defense

Dated: Washington, D.C.
_____, 2015

By: _____
ALAN P. SPIELMAN
Assistant Director of Federal Employee
Insurance Operations
United States Office of
Personnel Management

INSPIRE

LAKE FOREST, IL
Dated: Washington, D.C.
JUNE 10, 2015

By: 
JOSEPH BONACCORSI
Secretary
Inspire Pharmaceuticals, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Dated: Washington, D.C.
JUNE 11, 2015

By: 
JOHN T. BENTIVOGLIO
Skadden, Arps, Slate, Meagher & Flom LLP
1440 New York Avenue, N.W.
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Dated: Washington, D.C.
June 11, 2015

By:



MITCHELL S. ETTINGER

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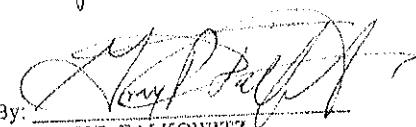
Attorney for Inspire Pharmaceutical, Inc.

RELATOR

DATED: 6/15

By: Jill DeGuzman
Jill DeGuzman

DATED: 6/3/15

By: 
GARY P. FALKOWITZ
Parker Waichman LLP
6 Harbor Park Drive
Port Washington, New York 11050
Attorney for Jill DeGuzman

SO ORDERED:

Souetta A. Preske
UNITED STATES DISTRICT JUDGE

June 15, 2015